JAN 2 1 2011

K101894

Bioremedi Therapeutic Systems, Inc ✪ 714 Center Hill Rd, Route 7a ✪ Copake, NY 12516
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SECTION 5.0 SUMMARY OF SAFETY & EFFECTIVENESS

This summary of 510 (k) safety and effectiveness information is being supplied in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92.

5.1 ADMINISTRATIVE INFORMATION

5.1.1 Sponsor Identification

BioRemedi Therapeutic Systems, Inc.
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Copake, NY 12516
Patrick Doyle
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5.1.2 Establishment Registration Number: 3006276091

5.1.3 Submission Correspondent

Norman F. Estrin, Ph.D.
Managing Partner
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5.1.4 Date Prepared: June 21, 2010

5.2 DEVICE NAME AND CLARIFICATION

5.2.1 Proprietary (Trade) Name: HealthLight™

5.2.2 Models: MicroController, MiniPro, ProNeuroLight, and Pro Unit

5.2.3	**Common Name:** LED light therapy device
5.2.4	**Classification Name: Lamp. Infrared, therapeutic Heating**
5.2.5	**Regulation Numbers: 21 CFR 890.5500**
5.2.6	**Proposed Regulation Class: Class II**
5.2.7	**Device Product Code: ILY**
5.2.8	**Medical Specialties: Physical Medicine**
5.3	**DEVICE DESCRIPTION** **The BioRemedi HealthLight™ is a scalable system consisting of seven different shaped/sized pads holding LEDs that may be used with any of three controllers, the differences being a two, a three or a four port configuration. Any pad, alone, or in any combination with any other pad, may be used with any of these three controllers.**
5.4	**INDICATIONS FOR USE** The BioRemedi HealthLight™ System is indicated for the following prescription uses • Provides heat therapy, i.e., temporarily relieves minor pain, stiffness, and muscle spasm. • Temporarily increases local blood circulation. It is indicated for Rx Only use.
5.5.1	**Predicate Device Name:** SMI™ SpectroPad
5.5.2	**Predicate Device FDA 510(k) Number: K931261**
5.6	**SUBSTANTIAL EQUIVALENCE** The BioRemedi HealthLight™ System is substantially equivalent to the predicate device, the SMI SpectroPad, (K931261). **Similarities** Anodyne (formerly SMI) and HealthLight™ are pulsed infrared devices using a separate controller to power flexible pads attached by a cable. Anodyne and HealthLight™ pads contain an array of light emitting diodes. Anodyne and HealthLight™ controllers are designed to power more than one pad at a time.

Anodyne and HealthLight™ are powered by plug packs converting mains power to 12VDC.

Differences
Anodyne (formerly SMI) is a solid-state device, HealthLight™ operates with a microprocessor.
Anodyne does not have a timer or auto shut off feature, HealthLight™ has a timer and an auto shut off feature after 30 minutes maximum.
Anodyne's design allows the controller to fail in an open or UNSAFE mode, HealthLight™ controller is designed to fail in a SAFE mode, i.e., shut off.
Anodyne cables use RCA connectors that are soldered to the input jacks, HealthLight™ cables use 5 pin DIN plugs that are removable from the device as commonly the case for electronic devices.
Anodyne solders the power supply lead to the power input connector,

HealthLight™'s power supply is removable, as is commonly the case for electronic devices.

HealthLight™ differs from the predicate device in that is a prescription only device while the predicate device is indicated for OTC use.

The differences identified above do not impact adversely the Safety and Effectiveness of the HealthLight™ device.

5.7 CONCLUSION

In summary, BioRemedi has demonstrated that its BioRemedi HealthLight™ System meets its specifications, is safe and effective for its intended use, and is substantially equivalent to the referenced predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

BioRemedi Therapeutic Systems, Inc.
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Potomac, Maryland 20854

JAN 21 2011

Re: K101894
Trade/Device Name: HealthLight™ MicroController, MiniPro, ProNeuroLight, and Pro Unit
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: January 09, 2011
Received: January 11, 2011

Dear Dr. Estrin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101894

Device Name: HealthLight™ MicroController, MiniPro, ProNeuroLight, and Pro Unit

Indications for Use:

HealthLight™ MicroController, MiniPro, ProNeurolLght, and Pro Unit are intended for the following indications for use:

1. Provides heat therapy, i.e., temporarily relieves minor pain, stiffness and muscle spasm.

2. Temporarily increases local blood circulation.

It is an Rx Only medical device.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

(Posted November 13, 2003)

510(k) Number K101894